Citation:

Hannum SM, Carson LA, Evans EM, Canene KA, Petr EL, Bui L, Erdman JW. Use of portion-controlled entrees enhances weight loss in women. Obes Res 2004; 12: 538-546.

Study Design:

Randomized Controlled Trial

Class:

A - Click here for explanation of classification scheme.

Research Design and Implementation Rating:

POSITIVE: See Research Design and Implementation Criteria Checklist below.

Research Purpose:

To determine the efficacy of a weight-loss diet using packaged portion-controlled entrees compared with a self-selected diet based on the USDA Food Guide Pyramid.

Inclusion Criteria:

Healthy women, BMI 26 - 40, 24 - 60 years old, access to microwave oven during the day, willingness to consume foods from all food groups.

Exclusion Criteria:

Excluded for use of cholesterol-lowering, hypertension or weight loss drugs, or any other drugs that affect weight or alter body composition, use of herbal supplements, pregnancy or lactation, strict vegetarian diet, smoking, diabetes, severe hypertension (defined as systolic BP > 159 and diastolic BP > 99 mm Hg), or other chronic disease states.

Description of Study Protocol:

Recruitment

Subjects recruited by means of a mailed flyer.

Design

Randomized parallel arm study.

Blinding used (if applicable)

Not used.

Intervention (if applicable)

Randomized to portion-controlled group or self-selected diet for 8 weeks. Subjects divided into diet groups by means of stratified randomization based on BMI, age, and activity level.

Statistical Analysis

Primary analysis was a per-protocol analysis. An intention-to-treat analysis was also conducted on body weight change using data from all individuals to determine both efficacy and acceptability of the weight loss regimen. For ITT analysis, missing data due to lack of follow-up were determined using "last value carried forward" approach. Effectiveness of randomization determined by Student's t test. Significant differences between both groups determined by repeated measures ANOVA. Based on power of 80%, sample size of 25 subjects per group would be required to find statistical differences. With estimated retention rate of 83%, 60 subjects were recruited.

Data Collection Summary:

Timing of Measurements

RD interviewed each subject before study to collect info on weight, height, blood pressure, health history and physical activity questionnaire. Baseline measurements taken. Each group met weekly to monitor compliance, take measurements, promote involvement and provide entrees.

Dependent Variables

- Weight measured using balance beam scale in street clothes without shoes or heavy outerwear
- Height determined using stadiometer
- Body composition by DXA
- Hip, waist, arm and thigh circumference assessed in triplicate using measuring tape
- Blood pressure measured with standard sphygmomanometer on subjects who had been seated for 5 minutes
- Fasting blood samples drawn on 2 consecutive days and averaged. Each blood sample analyzed for basic metabolic panel, insulin, lipid panel and C-reactive protein

Independent Variables

- Portion-controlled group consumed 2 Uncle Ben's Bowls frozen entrees (lunch and dinner) daily plus additional food servings from Food Guide Pyramid. Self-selected diet group consumed a recommended number of servings from Food Guide Pyramid. Both diets designed to be 1365 kcal, 55% carbohydrate, 25% protein, 20% fat. Both groups given straightforward instruction but no individual behavioral and diet counseling. Compliance monitored through 3-day food records submitted every 2 weeks as well as weekly interviews.

Control Variables

- Activity level assessed by 2-day activity diary. Records compared from baseline and endpoint to determine consistency during study

Description of Actual Data Sample:

Initial N: 60 women recruited.

Attrition (final N): 53 completed the study. 26 in portion-controlled group and 27 in self-selected diet. 2 subjects lost to follow-up (loss of interest and illness), 5 subjects were protocol violators (lack of attendance, lack of record keeping, lack of adherence to diet). Total compliance based on attendance, completion of written records, and dietary adherence. Subjects falling below 70% compliance in any area were dropped.

Age: Portion-controlled group: 37.5 +/- 9.7 years (range 24-55). Self-selected diet group: 36.6 +/- 9.4 years (range 24 - 56).

Ethnicity: 41 whites, 9 African Americans and 3 other ethnic groups. Portion controlled group: 19 whites, 7 minorities. Self-selected diet: 22 whites, 5 minorities.

Other relevant demographics:

Anthropometrics: There were no differences between groups in BMI, age, waist circumference and activity level.

Location: Champagne-Urbana, Illinois

Summary of Results:

	Self-Select Baseline	Self-Select 8 weeks	Change	Portion Control Baseline	Portion Control 8 weeks	Change
Energy (kcal)	1760 +/- 603	1290 +/- 282	-470 +/- 516	**1958.1 +/- 497.4**	**1305.9 +/- 185.4**	**-652 +/- 408**
Body Weight (kg)	85.3 +/- 11.2	81.7 +/- 11.3	-3.6 +/- 2.5	**86.7 +/- 13.3**	**81.1 +/- 12.7**	**-5.6 +/- 2.2**
BMI	31.6 +/- 3.3	30.3 +/- 3.4	-1.3 +/- 0.9	**31.8 +/- 3.5**	**29.7 +/- 3.5**	**-2.0 +/- 0.8**
Body Fatness (%)	40.1 +/- 3.9	39.0 +/- 4.1	-1.2 +/- 0.8	**40.3 +/- 4.1**	**38.6 +/- 4.3**	**-1.7 +/- 1.1**
Fat Mass (kg)	34.6 +/- 7.2	32.3 +/- 7.2	-2.3 +/- 1.4	**35.3 +/- 7.8**	**31.8 +/- 7.2**	**-3.6 +/- 1.8**
Lean Mass (kg)	51.0 +/- 5.2	50.0 +/- 5.5	-1.0 +/- 0.9	**51.7 +/- 6.5**	**49.8 +/- 6.7**	**-1.8 +/- 1.3**
Trunk Fat Mass (kg)	16.1 +/- 4.0	15.0 +/- 3.9	-1.1 +/- 0.9	**15.4 +/- 4.1**	**13.6 +/- 3.9**	**-1.9 +/- 1.2**
Waist circumference (cm)	99.9 +/- 11.2	98.6 +/- 12.3	-1.3 +/- 3.5	**100.8 +/- 9.2**	**96.9 +/- 9.0**	**-3.9 +/- 4.5**
Hip circumference (cm)	112.7 +/- 6.3	110.5 +/- 7.0	-2.2 +/- 2.6	**117.5 +/- 9.0**	**112.9 +/- 8.7**	**-4.5 +/- 1.9**
Arm circumference (cm)	35.5 +/- 3.3	34.0 +/- 3.2	-1.5 +/- 1.0	**35.0 +/- 3.2**	**33.0 +/- 3.0**	**-2.0 +/- 0.8**
Thigh circumference (cm)	63.8 +/- 5.4	61.4 +/- 4.6	-2.3 +/- 2.2	**65.7 +/- 5.5**	**63.0 +/- 6.0**	**-2.7 +/- 2.6**

Other Findings

The portion-controlled group (n=26) experienced greater decreases in weight (5.6 +/- 2.2 kg or

6.5% vs 3.6 +/- 2.5 kg or 4.2%, p < 0.01), fat mass (3.6 +/- 1.8 vs 2.3 +/- 1.4 kg, p = 0.05), total cholesterol (24.4 +/- 21.5 mg/dl or 12.4% vs 13.0 +/- 13.9 mg/dl or 6.7%, p <0.05) and fasting insulin (-1.8 +/- 3.7 vs 0.3 +/- 3.8 microU/ml, p < 0.05) than the self-selected diet group (n=27).

Author Conclusion:

The results of this study indicate that consumption of portion-controlled entrees as part of a balanced low-calorie diet resulted in greater losses of weight and fat, thereby reducing cardiovascular disease risk. Accurate portion control is an important factor in weight loss success, and is easier to achieve with packaged entrees.

Reviewer Comments:

Compliance monitored through 3-day food records and weekly interviews.

Research Design and Implementation Criteria Checklist: Primary Research

Relevance Questions

1.	Would implementing the studied intervention or procedure (if found successful) result in improved outcomes for the patients/clients/population group? (Not Applicable for some epidemiological studies)	Yes
2.	Did the authors study an outcome (dependent variable) or topic that the patients/clients/population group would care about?	Yes
3.	Is the focus of the intervention or procedure (independent variable) or topic of study a common issue of concern to nutrition or dietetics practice?	Yes
4.	Is the intervention or procedure feasible? (NA for some epidemiological studies)	Yes

Validity Questions

1.	**Was the research question clearly stated?**	Yes
1.1.	Was (were) the specific intervention(s) or procedure(s) [independent variable(s)] identified?	Yes
1.2.	Was (were) the outcome(s) [dependent variable(s)] clearly indicated?	Yes
1.3.	Were the target population and setting specified?	Yes
2.	**Was the selection of study subjects/patients free from bias?**	Yes
2.1.	Were inclusion/exclusion criteria specified (e.g., risk, point in disease progression, diagnostic or prognosis criteria), and with sufficient detail and without omitting criteria critical to the study?	Yes
2.2.	Were criteria applied equally to all study groups?	Yes

2.3.	Were health, demographics, and other characteristics of subjects described?	Yes
2.4.	Were the subjects/patients a representative sample of the relevant population?	Yes
3.	**Were study groups comparable?**	Yes
3.1.	Was the method of assigning subjects/patients to groups described and unbiased? (Method of randomization identified if RCT)	Yes
3.2.	Were distribution of disease status, prognostic factors, and other factors (e.g., demographics) similar across study groups at baseline?	Yes
3.3.	Were concurrent controls used? (Concurrent preferred over historical controls.)	Yes
3.4.	If cohort study or cross-sectional study, were groups comparable on important confounding factors and/or were preexisting differences accounted for by using appropriate adjustments in statistical analysis?	N/A
3.5.	If case control or cross-sectional study, were potential confounding factors comparable for cases and controls? (If case series or trial with subjects serving as own control, this criterion is not applicable. Criterion may not be applicable in some cross-sectional studies.)	N/A
3.6.	If diagnostic test, was there an independent blind comparison with an appropriate reference standard (e.g., "gold standard")?	N/A
4.	**Was method of handling withdrawals described?**	Yes
4.1.	Were follow-up methods described and the same for all groups?	Yes
4.2.	Was the number, characteristics of withdrawals (i.e., dropouts, lost to follow up, attrition rate) and/or response rate (cross-sectional studies) described for each group? (Follow up goal for a strong study is 80%.)	Yes
4.3.	Were all enrolled subjects/patients (in the original sample) accounted for?	Yes
4.4.	Were reasons for withdrawals similar across groups?	Yes
4.5.	If diagnostic test, was decision to perform reference test not dependent on results of test under study?	N/A
5.	**Was blinding used to prevent introduction of bias?**	No
5.1.	In intervention study, were subjects, clinicians/practitioners, and investigators blinded to treatment group, as appropriate?	No
5.2.	Were data collectors blinded for outcomes assessment? (If outcome is measured using an objective test, such as a lab value, this criterion is assumed to be met.)	No

5.3.	In cohort study or cross-sectional study, were measurements of outcomes and risk factors blinded?	N/A
5.4.	In case control study, was case definition explicit and case ascertainment not influenced by exposure status?	N/A
5.5.	In diagnostic study, were test results blinded to patient history and other test results?	N/A
6.	**Were intervention/therapeutic regimens/exposure factor or procedure and any comparison(s) described in detail? Were interveningfactors described?**	Yes
6.1.	In RCT or other intervention trial, were protocols described for all regimens studied?	Yes
6.2.	In observational study, were interventions, study settings, and clinicians/provider described?	N/A
6.3.	Was the intensity and duration of the intervention or exposure factor sufficient to produce a meaningful effect?	Yes
6.4.	Was the amount of exposure and, if relevant, subject/patient compliance measured?	Yes
6.5.	Were co-interventions (e.g., ancillary treatments, other therapies) described?	Yes
6.6.	Were extra or unplanned treatments described?	Yes
6.7.	Was the information for 6.4, 6.5, and 6.6 assessed the same way for all groups?	Yes
6.8.	In diagnostic study, were details of test administration and replication sufficient?	N/A
7.	**Were outcomes clearly defined and the measurements valid and reliable?**	Yes
7.1.	Were primary and secondary endpoints described and relevant to the question?	Yes
7.2.	Were nutrition measures appropriate to question and outcomes of concern?	Yes
7.3.	Was the period of follow-up long enough for important outcome(s) to occur?	Yes
7.4.	Were the observations and measurements based on standard, valid, and reliable data collection instruments/tests/procedures?	Yes
7.5.	Was the measurement of effect at an appropriate level of precision?	Yes
7.6.	Were other factors accounted for (measured) that could affect outcomes?	Yes
7.7.	Were the measurements conducted consistently across groups?	Yes
8.	**Was the statistical analysis appropriate for the study design and type of outcome indicators?**	Yes

8.1.	Were statistical analyses adequately described and the results reported appropriately?	Yes
8.2.	Were correct statistical tests used and assumptions of test not violated?	Yes
8.3.	Were statistics reported with levels of significance and/or confidence intervals?	Yes
8.4.	Was "intent to treat" analysis of outcomes done (and as appropriate, was there an analysis of outcomes for those maximally exposed or a dose-response analysis)?	Yes
8.5.	Were adequate adjustments made for effects of confounding factors that might have affected the outcomes (e.g., multivariate analyses)?	Yes
8.6.	Was clinical significance as well as statistical significance reported?	Yes
8.7.	If negative findings, was a power calculation reported to address type 2 error?	N/A
9.	**Are conclusions supported by results with biases and limitations taken into consideration?**	Yes
9.1.	Is there a discussion of findings?	Yes
9.2.	Are biases and study limitations identified and discussed?	Yes
10.	**Is bias due to study's funding or sponsorship unlikely?**	Yes
10.1.	Were sources of funding and investigators' affiliations described?	Yes
10.2.	Was the study free from apparent conflict of interest?	Yes